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Mechanical Engineer

Location: **Minneapolis, MN**

Department: **Research & Development**

Employment Duration: **Full Time Regular**

FLSA Status: **Exempt**

Description

AtriCure, Inc is a medical device company that provides innovative solutions designed to decrease the global Afib epidemic. AtriCure's Isolator® Synergy™ Ablation System is the first and only surgical device approved for the treatment of persistent and longstanding persistent forms of Afib in patients undergoing certain open concomitant procedures. AtriCure's AtriClip® Left Atrial Appendage Management (LAAM) exclusion device is the most widely sold device worldwide that is indicated for the occlusion of the left atrial appendage. AtriCure believes electrophysiologists and cardiothoracic surgeons are adopting its technologies for the treatment of Afib and reduction of Afib related complications. Afib affects more than 33 million people worldwide. For more information, visit AtriCure.com or follow us on Twitter @AtriCure.

POSITION SUMMARY:

The Mechanical Engineer contributes to the development of ablation products that treat atrial fibrillation. Job performance requires application of technical abilities, knowledge of mechanical engineering and materials science, and an understanding of product development methodologies. Deliverable outputs include analysis, design, evaluation, production transfer, and documentation of products that meet medical

and regulatory guidelines. Most work will be performed in the context of multi-disciplinary teams and under the direction of a senior engineer or project manager.

ROLES AND RESPONSIBILITIES:

- Design, develop, analyze, and test medical/surgical components, equipment, and instruments
- Develop product performance requirements as well as assembly and component specifications
- Perform analytical modeling / analysis of new technologies and design implementations in support of achieving clinical outcomes
- Serve as a technical resource for materials science applications in product development
- Conduct laboratory activities related to new product development, including in-vitro and in-vivo studies
- Provide analysis, testing, and reporting to predict and verify the human body response to designed devices
- Contribute to improvement in methods and processes of the product development organization
- Generate and document intellectual property

BASIC QUALIFICATIONS:

- BS in Mechanical Engineering or Materials Science
- 3 years of experience in mechanical engineering or similar field
- Understanding of development life cycle including needs assessment, technology development, detail design & manufacturing systems development, regulatory requirements, and product verification / validation
- Proficiency acting in integrated process/product teams, as well as coordinating and communicating customer requirements
- A track record of:
 - Creative problem solving
 - Evaluating user needs and generating solutions
 - Prioritizing tasks and producing deliverables per schedule expectations
 - Completion of significant and broad tasks with limited direct supervision
 - Demonstrated proficiencies of communicating best practices
- Experience and success working in team environment
- Excellent written and oral communication skills
- Experience with data analysis, problem-solving, troubleshooting, and formal root cause analysis
- Experience in test method development and validation
- Experience in execution of verification tests and generating test reports
- Ability to read and create technical specifications, blueprints, and drawings
- Familiarity with:
 - Materials Science as it pertains to medical device development
 - Design Controls and experience with FDA QSR 21 CFR Part 820 and ISO 13485
 - External Standards, Design controls, Quality controls, Manufacturing methods
 - Statistical methods

PREFERRED QUALIFICATIONS:

- MS in Mechanical Engineering or Materials Science
- 5 years of experience in mechanical engineering or similar field

- Experience in mechanical engineering for medical device product development
- Expertise in Materials Science for medical device development
- Excellent demonstrated ability with statistics-based data analysis, problem-solving, and troubleshooting
- Track record of managing technical development tasks exhibiting comprehensive planning and thorough communication
- Excellent understanding of medical device industry regulations and PMA/510(k) medical device development
- Excellent understanding of external standards, design controls, quality controls, manufacturing methods
- Proven track record of generating and documenting intellectual property
- Experience with International Usability Standards and the practical application of Usability Engineering
- Experience in defining and execute verification or manufacturing tests
- Experience in Industrial Design
- Solid understanding of:
 - Cardiac anatomy, physiology, and biophysics
 - In-vitro and in-vivo lab activities

ESSENTIAL JOB FUNCTIONS:

- This position is in an office / lab environment including working at a desk / on a computer for extended times
- Position will involve working in a lab environment with tissue
- Position will involve walking, sitting, standing, bending, pushing and pulling on a regular basis, and will involve lifting items up to 25 pounds on a regular basis, and up to 50 pounds on an occasional basis
- 10% travel possibility
- Position contingent upon candidate passing pre-employment physical/drug screen

All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, national origin, age, protected veteran status, status as an individual with disability, sexual orientation or gender identity.

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Agency and Third Party Recruiter Notice:

Agencies that submit a resume to AtriCure must have a current Agreement in place, executed by a member of the Human Resource/Recruiting Department. In addition agencies may only submit candidates to positions for which they have been invited to do so by one of our Recruiters or Recruiting Managers. All unsolicited resumes sent to us will be considered property of AtriCure and AtriCure will not be held liable to pay a placement fee.

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AtriCure, Inc. is a medical device company providing innovative atrial fibrillation (Afib) solutions designed to produce superior outcomes that reduce the economic and social burden of Afib.

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